K010482

EchoCath Inc.
Special 510(k) Submission
EchoFlow Doppler Blood Velocity Meter
510(k) Summary

(1) Submitters name, address, telephone number, contact person, and date of preparation

Name: EchoCath Inc.
Address: PO Box 7224
Princeton, NJ 08543
Telephone Number: 609-987-8400
Contact person:

Dr. George H. Myers
Medsys Inc
377 Route 17
Hasbrouck Heights NJ 07604

201-727-1703 fax: 201-727-1708

Date of preparation: January 30, 2001

(2) Names

Trade name: EchoFlow Portable Doppler Blood Velocity Meter
Common Name: Doppler ultrasonic blood-flow measuring system
Classification Name: Flowmeter, blood, ultrasonic, w/wo calibration, and Transducer, Ultrasonic

(3) Predicate devices:

EchoFlow Doppler Flow Meter, K990642,

(4) Description

The EchoFlow Portable velocity system is a computer-based portable ultrasonic Doppler blood velocity measuring system used to measure blood velocity in vessels that are located as far as 0.9 cm from the probe (depending on the attenuation of the intervening tissue) or in contact with it. It can either be used for measurement on the surface of the skin, or for intraoperative measurements. A 10 MHz CW probe is used. When used intraoperatively, a sterile sheath covers the probe and 6 feet of cable coming from the probe.

A unique feature of the system is that the angle between the probe and the axis of the blood vessel does not have to be known. An accuracy of 15% is maintained if this

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angle changes by as much as ±15°. This is done by using a unique probe that emits two beams at known angles with respect to each other, as explained in a later section. Thus, the system is well-adapted to measuring flow in blood vessels beneath the surface of the skin, where the exact angle of the axis of the blood vessel cannot be determined.

(5) Intended Use

The EchoFlow velocity system is intended to be used to measure blood velocity in vessels that are located as far as 0.9 cm from the probe (depending on the attenuation of the intervening tissue) or in contact with it. It can either be used for measurement on the surface of the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. It is indicated when a portable device is needed.

(6) Comparison to Predicate Devices

(a) The EchoFlow system has the same intended use, method of application, and clinical utility as the predicate device. It differs from it in that it is a portable device.

(b) Performance data

(1) Non-clinical tests:

The portable Doppler meets the requirements for

Doppler accuracy
Software validation
Depth penetration
Ultrasonic emissions tests

(2) Clinical test

Not required

(3) Conclusions

The conclusions drawn from the tests demonstrate that the device is as safe and effective, and performs as well or better than the legally marketed device identified in paragraph 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Mr. Frank De Bernardis
President
EchoCath Inc.
P.O. Box 7224
Princeton, NJ 08543

Re: K010482
Trade Name: EchoFlow Portable Doppler Blood Velocity Meter and Transducer for Portable EchoFlow Doppler Blood Velocity Meter
Regulatory Class: II
Product Code: JOP, CAS
Regulation: 21 CFR 870.2880
Dated: February 15, 2001
Received: February 20, 2001

Dear Mr. De Bernardis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Diagnostic Ultrasound Indications for Use Form

Device Name: EchoFlow Portable Doppler Blood Velocity Meter

Indications for Use:

The EchoFlow Portable velocity system is intended to be used to measure blood velocity in vessels that are located as far as 9 mm from the probe (depending on the attenuation of the intervening tissue) or in contact with it. It can either be used for measurement on the surface of the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. It is indicated when a portable device is needed.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

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Diagnostic Ultrasound Transducer Indications for Use Form

Device Name: Transducer for Portable EchoFlow Doppler Blood Velocity Meter

Indications for Use:

The transducer for the Portable EchoFlow Doppler Blood Velocity meter is intended to be used with that unit. The EchoFlow velocity system is intended to be used to measure blood velocity in vessels that are located as far as 9 mm from the probe (depending on the attenuation of the intervening tissue) or in contact with it. It can either be used for measurement on the surface of the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. It is indicated when a portable device is needed.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

3/20/1

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